Amendments to the Claims:

Please amend claims 42-47 as follows.

Please add new claims 48 and 49.

Please cancel claims 4-41 without prejudice.

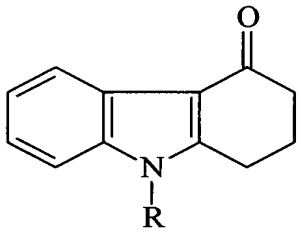
Claim 1 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0%.

Claim 2 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5%.

Claim 3 (previously amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9%.

Claim 4 (cancel) A process for preparing dimethylamino-methyl-carbazolone comprising the steps of:

a) preparing a solution of methyl-carbazolone having the formula:



(where R = C_{1-4}, alkyl)

b) heating the solution in the presence of dimethylamine hydrochloride and paraformaldehyde;

c) basifying the solution to form a precipitate;

d) separating the precipitate from the solution;

e) drying the precipitate.

Claim 5 (cancel) The process according to claim 4, wherein R is methyl.

Claim 6 (cancel) The process according to claim 4, wherein the heating step is performed at a temperature of about 70^0C to about 100^0C.

Claim 7 (cancel) The process according to claim 4, wherein the heating step is performed at a temperature of about 80^0C to about 90^0C.

Claim 8 (cancel) The process according to claim 4, wherein the heating step is

performed for about 6 to about 24 hours.

Claim 9 (cancel) The process according to claim 4, wherein the heating step is performed for about 6 to about 12 hours.

Claim 10 (cancel) The process according to claim 4, wherein the heating step is performed in acetic acid.

Claim 11 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and paraformaldehyde.

Claim 12 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.

Claim 13 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.1 to about 1.5 equivalents of dimethylamine hydrochloride and formaldehyde.

Claim 14 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 1.2 equivalents of dimethylamine hydrochloride and formaldehyde.

Claim 15 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 to about 6 volumes of acetic acid.

Claim 16 (cancel) The process according to claim 4, wherein about one equivalent methyl-carbazolone is heated in the presence of about 4 volumes of acetic acid.

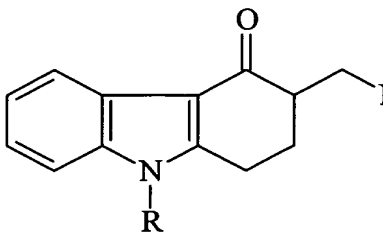
Claim 17 (cancel) The process according to claim 4, wherein the solution of methyl-carbazolone is basified by about 45% sodium hydroxide.

Claim 18 (cancel) The process according to claim 17, wherein the solution is basified to a pH of about 13 to about 14.

Claim 19 (cancel) The process according to claim 17 or 18, wherein the basifying step is performed in the presence of 10% celite.

Claim 20 (cancel) A process for preparing ondansetron base, comprising the steps of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



(where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondasetron base from the solution;

d) washing the precipitate;

e) drying precipitate to obtain ondansetron base.

Claim 21 (cancel) The process according to claim 20, wherein the solution is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 22 (cancel) The process according to claim 20, wherein the solution is prepared by adding about 5 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 23 (cancel) The process according to claim 20, wherein the solution is prepared in the presence of 10% celite.

Claim 24 (cancel) The process according to claim 20, further comprising the step of: recrystallizing ondansetron base.

Claim 25 (cancel) The process according to claim 24, wherein the recrystallizing step is performed in the presence of activated carbon and methanol.

Claim 26 (cancel) A process of preparing pure ondansetron hydrochloride dihydrate comprising the steps of:

a) preparing a solution of ondansetron base;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate.

Claim 27 (cancel) The process according to claim 26 wherein about 3 to about 7 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.

Claim 28 (cancel) The process according to claim 26 wherein about 5 volumes of water is added to ondansetron base to prepare a solution of ondansetron base.

Claim 29 (cancel) The process according to claim 26 wherein about 1.0 to about 1.4 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.

Claim 30 (cancel) The process according to claim 26 wherein about 1.1 equivalents of about 32% (v:v) hydrochloric acid is added to acidify the solution to induce precipitation.

Claim 31 (cancel) The process of claims 29 or 30, wherein the solution is acidified to a pH about 1 to about 4.

Claim 32 (cancel) The process of claims 29 or 30, wherein the solution is acidified to a pH about 3.

Claim 33 (cancel) The process according to claim 26, wherein the precipitate is washed with about 5 to about 15 ml of isopropanol.

Claim 34 (cancel) The process according to claim 26, wherein the precipitate is washed with about 10 ml of isopropanol.

Claim 35 (cancel) The process according to claim 26, wherein the crystallizing step is achieved by adding about 3 to about 5 volumes of water to induce crystallization.

Claim 36 (cancel) The process according to claim 26, wherein the crystallizing step is achieved by adding about 4 volumes of water to induce crystallization.

Claim 37 (cancel) The process according to claim 26, wherein the crystallization step is repeated two times.

Claim 38 (cancel) The process according to claim 26, wherein the crystallizing step is achieved in the presence of activated carbon.

Claim 39 (cancel) The process according to claim 36, wherein the activated

carbon is selected from the group consisting of SX-2, CA-1,CXV and SX-1.

Claim 40 (cancel) The process according to claim 39, wherein the activated carbon is about 5 to about 15% SX-1.

Claim 41 (cancel) The process according to claim 39, wherein the activated carbon is about 5 to about 10% SX-1.

Claim 42 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has~~ having a purity of at least about 99.0% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 43 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate have~~ having a purity of at least about 99.5% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 44 (currently amended) Ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26, wherein the ondansetron hydrochloride dihydrate has~~ having a purity of at least about 99.9% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

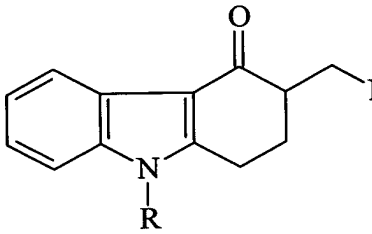
Claim 45 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
a) preparing a solution of ondansetron base in water;
b) acidifying the solution with hydrogen chloride to form a precipitate;
c) washing the precipitate; and
d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 46 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
a) preparing a solution of ondansetron base in water;
b) acidifying the solution with hydrogen chloride to form a precipitate;
c) washing the precipitate; and
d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 47 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate ~~as prepared in accordance with a process of claim 26~~, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:
a) preparing a solution of ondansetron base in water;
b) acidifying the solution with hydrogen chloride to form a precipitate;
c) washing the precipitate; and
d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 48 (new) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



(where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

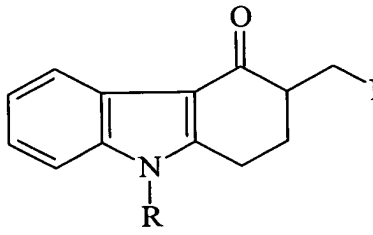
d) washing the precipitate;

e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 49 (new) The pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as in claim 45, 46, or 47, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



(where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

d) washing the precipitate;

e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.